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Inventor Application of:

David D. Mundschenk

Serial No.: 09/240,455

Filed: 29 January 1999

For: BUCCAL DELIVERY SYSTEM

)  
) Attorney Docket: 15050.5.0  
)  
) Group Art Unit: 1615  
)  
) Examiner: Todd Ware  
)

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on this 27 day of August, 2002

By Madely E. Thonry

PRELIMINARY AMENDMENT

This Amendment is filed in response to the Final Office Action mailed March 27, 2002, the period for response to which has been extended to August 27, 2002 by the accompanying Petition For Extension of Time, and together with the enclosed Request for Continued Examination (RCE).

Remarks

Claims 1 and 3-69 are pending.

The rejection of claims 1, 3-4, 9-50 and 52-69 under Section 103(a) is respectfully traversed. Mundschenk '407 is cited for its teaching of the preparation of inactivated bioactive peptides, while Heiber et al. is cited as teaching "buccally administered peptides", and Dondeti et al. and Siegel et al. are cited, essentially, for their inclusion of benzalkonium chloride in delivery compositions (though in each case as "preservatives").

None of the cited references, however, either alone or in suitable combination, teach or suggest the use of a quaternary ammonium salt (such as benzalkonium chloride) to *itself* provide effective permeation of an *inactivated bioactive peptide* into a mucosal surface, and particularly into a mucosal surface of the mouth.